

PACKAGE LEAFLET: INFORMATION FOR THE USER

Ca-C 1000 Calvive

1000 mg + 327 mg + 1000 mg effervescent tablets

CALCIUM LACTATE GLUCONATE, CALCIUM CARBONATE, ASCORBIC ACID (VITAMIN C)

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• Keep this leaflet • You may need to read it again • If you have any further questions, ask your doctor or pharmacist • This medicine has been prescribed for you only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What CA-C 1000 CALVIVE is and what it is used for
2. Before you take CA-C 1000 CALVIVE
3. How to take CA-C 1000 CALVIVE
4. Possible side effects
5. How to store CA-C 1000 CALVIVE
6. Further information

1. WHAT CA-C 1000 CALVIVE IS AND WHAT IT IS USED FOR

Ca-C 1000 Calvive contains three active substances two of which are calcium salts (calcium lactate gluconate and calcium carbonate), and the third is ascorbic acid (vitamin C).

Calcium is an essential mineral, necessary for building and maintaining the bones. It is essential for most of the bodily functions, essential for nerve, muscle, heart function and blood clotting. Calcium is a mediator of the effects of numerous hormones. To perform these functions, calcium needs to be present in certain tissues in sufficient amounts.

Ascorbic acid (vitamin C) plays an important role in biochemical processes. It is also necessary for the formation of collagen (found in bone, cartilage, skin and other tissues) and tissue regeneration.

High doses of vitamin C are considered to be effective in the prevention and treatment of upper respiratory tract infections.

Ca-C 1000 Calvive is used when there is the lack of calcium and ascorbic acid which may be due to improper diet or increased need for calcium and vitamin C:

- during pregnancy and breastfeeding
- during the period of rapid growth in children and adolescents
- during the old age

- during the infectious diseases
- during the healing process

Ca-C 1000 Calvive effervescent tablets provide vitamin C and calcium in amounts sufficient to meet the daily needs during the periods when the need for them is increased.

Ca-C 1000 Calvive can also be used as an auxiliary product for the treatment of colds and flu.

2. BEFORE YOU TAKE CA-C 1000 CALVIVE

Do not take CA-C 1000 CALVIVE

- If you are allergic (hypersensitive) to any ingredient of this medicine (all ingredients are listed in section 6);
- If you have hypercalcemia (increased levels of calcium in the blood);
- If you have hypercalciuria (increased levels of calcium in the urine);
- If you have kidney problems, including kidney stones (nephrolithiasis) and the accumulation of calcium in the kidney (nephrocalcinosis);

Take special care with CA-C 1000 CALVIVE

- If you have increased levels of calcium in the urine (hypercalciuria) with mild to moderate renal impairment or if you have excreted kidney stones through urine.
In these cases it is recommended to drink lots of fluids. If necessary, your doctor will reduce the dose or interrupt treatment.
- If you have high levels of oxalic acid in the urine
- If you suffer from kidney disorders, take Ca-C 1000 Calvive only after consulting with your doctor or pharmacist, especially if you are taking the preparations containing aluminum. In the case of kidney failure, consult your doctor or pharmacist before taking vitamin C.
- If you have diabetes or if you are on a diet that involves reduced sodium intake.
- You should avoid high doses of vitamin D and its derivatives during the treatment with Ca-C 1000 Calvive, unless your doctor has prescribed so.

Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription.

Before you take Ca-C 1000 Calvive tablets, tell your doctor if you are taking any of the following medications:

- Thiazide diuretics (medicines for promoting excretion of urine, used for treating high blood pressure or a condition in which the body retains too much fluid, eg. heart failure);
- Systemic corticosteroids (anti-inflammatory medicines);
- Cardiac glycosides (medicines containing digitalis, used in heart failure);
- Preparations containing tetracyclines (antibiotics). They should be taken at least 2 hours before or 4-6 hours after taking the medicine Ca-C 1000 Calvive.
- Oral bisphosphonates (used to treat problems with the bones) or sodium fluoride. They should be taken at least 3 hours before taking the medicine Ca-C 1000 Calvive.
- Simultaneously taking calcium with vitamin D or its derivatives enhances calcium absorption.
- aluminum-based antacids (used to neutralize the stomach acid);
- Deferoxamine (used to remove excess iron from the body).

Before simultaneously taking other vitamins, vitamin-mineral and / or mineral products, consult a doctor or pharmacist.

Do not take more than 1 g of vitamin C because it can cause false test results of blood and urine (eg. the test for determining glucose).

Taking CA-C 1000 CALVIVE with food and drink

The absorption of calcium may be reduced due to consumption of certain foods such as spinach, rhubarb and whole grains. Calcium preparations should not be taken within 2 hours after consumption of those foods.

Pregnancy and breast-feeding

Ca-C 1000 Calvive can be taken during pregnancy and breastfeeding in case of a lack of calcium. The total daily intake of calcium during the last trimester of pregnancy should not be higher than 1500 mg.

Immediately contact your doctor or pharmacist in the case of overdose of calcium during the pregnancy because it can have harmful effects on the fetus.

Do not take more than the recommended dosage during pregnancy because exposure to high doses of vitamin C in the prenatal period may cause symptoms of deficiency in neonates and infants. Calcium and vitamin C exceed into breast milk, but do not have adverse effects on the infant.

Before using the medicine, it is necessary to consult a doctor.

Driving and using machines

CA-C 1000 CALVIVE should not affect your ability to drive and use machines.

Other warnings

Ca-C 1000 Calvive contains:

- Sucrose; if your doctor says that you have the so called intolerance to some sugars, before you start taking this medicine, consult your doctor.
- Sodium; if you are on a diet that includes reduced sodium intake, you need to know that an effervescent tablet Ca-C 1000 Calvive contains 0.28 g of sodium.

Information for diabetics

One Ca-C 1000 Calvive effervescent tablet contains 2 g of sugar.

3. HOW TO TAKE CA-C 1000 CALVIVE

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults and children aged 7 years and older: 1 effervescent tablet per day.

Children from 3 to 7 years: 1/2 effervescent tablet per day.

Children under 3 years: only on the recommendation of a doctor.

Dissolve effervescent tablet in a glass of water (approximately 200 ml) and drink immediately.

Ca-C 1000 Calvive effervescent tablets can be taken with or without food.

If you take more CA-C 1000 CALVIVE than you should

Overdose can cause high levels of calcium in the urine (hypercalciuria) and high levels of calcium in the blood (hypercalcemia). Symptoms of high levels of calcium in the blood may include: nausea, vomiting, thirst, excessive drinking of liquids, increased urination, dehydration and constipation. Prolonged overdose with increased level of calcium in the blood can lead to the storage of calcium in the body. High doses of vitamin C can cause diarrhea and blood disorders such as hemolysis (bursting of red blood cells).

In case of overdose, immediately contact your doctor.

If you forget to take CA-C 1000 CALVIVE

Do not take a double dose to make up for the forgotten tablet.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, CA-C 1000 CALVIVE can cause side effects, although not everybody gets them.

Stop taking Ca-C 1000 Calvive and Seek immediate medical attention if you or your child experience any of the following symptoms which may be signs of allergic reaction:

- difficulty breathing and swallowing
- swelling of the face, lips, tongue or throat
- severe itching of the skin with red rash or protuberances

These side effects are rare or very rare (occur in 1 to 10 out of 10,000 patients).

Some side effects are uncommon (may occur in up to 1 to 10 of 1000 patients):

- high level of calcium in the blood (hypercalcemia)
- high level of calcium in the urine (hypercalciuria)

Some side effects are rare (occur in 1 to 10 out of 10,000 patients):

- abdominal bloating and gas (flatulence), constipation, diarrhea, nausea, vomiting, abdominal pain, rash, pruritus, urticarial

Other possible side effects which frequency cannot be determined on the basis of available data:

- formation of stones in the kidneys or bladder (during the long-term use of high doses of calcium and vitamin C)

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE CA-C 1000 CALVIVE

Keep out of the reach and sight of children.

This medicine should no longer be used after the expiry date printed on the container. The expiry date is the last day of the month indicated.

Do not store above 25 °C. Store in the original package protected from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What CA-C 1000 CALVIVE contains

The active substances are calcium lactate gluconate, calcium carbonate and ascorbic acid (vitamin C).

One effervescent tablet Ca-C 1000 Calvive contains 1000 mg of calcium lactate gluconate and 327 mg of calcium carbonate (corresponding to 260 mg of ionic calcium) and 1000 mg of ascorbic acid (vitamin C).

Other ingredients are sucrose; sodium hydrogencarbonate; Citric acid, anhydrous; macrogol 4000; Saccharin sodium; beta-carotene; aroma of bitter orange (maltodextrin, gum arabic, sorbitol (E420), essential oils 20-25%, D-limonene and natural β -pinene), lemon flavor (corn maltodextrin, α -tocopherol (E307) and natural flavors).

What CA-C 1000 CALVIVE looks like and contents of the pack

Yellow, round effervescent tablets flat surfaces and rounded edges with orange spots and the scent of lemon. Effervescent tablets are packaged in a polypropylene tube with a polyethylene cap containing a desiccant, in a box.

One tube contains 10 effervescent tablets.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Novartis Consumer Health SA

Route de l'Etraz, 1260 Nyon, Switzerland